REMARKS/ARGUMENTS

Background

In different aspects, the invention differs from the cited items by employing mixtures of anti-PCMs from different cancer cell lines as a reagent and/or by employing simple ELISA as the assay technique. The invention fulfills a long-felt but unsolved need for a simple, inexpensive screening test for cancer.

Summary of Amendments, support, status of claims

Claims 1, 2, 4, 5, 6, 13, 15, 17, 18, 20, 21, and 22 are amended. Claims 1-23 are pending and have been rejected.

Claim 1 is amended to recite that the markers are from "different cell lines". The amendment is fairly supported at page 6, lines 4-6.

Claim 2 is amended to recite that the "saliva sample is coated on the plate prior to being brought together with the reagent". The amendment is fairly supported at page 8, lines 24-25.

Claim 4 is amended to make clear that antibodies can be formed against a mixture of PCMs. The amendment is fairly supported at page 7, lines 34-36.

Claim 5 is amended for consistency with claim 4.

Claim 6 is amended to more clearly define a mixture of PCMs. The amendment is fairly supported at page 7, lines 34-36.

Claim 14 is amended for consistency with claim 4.

Claim 17 is amended similarly to claim 2.

Claim 18 is amended similarly to claim 4. Support for the Markush group is found at page 5, lines 9-13.

Claim 20 is amended for clarity. The phrase "above a predetermined value" is supported by original claim 19, for example.

Claim 21 is amended along the lines of claim 2.

Rejections under 35 USC 102

Claims 1-3, 11-12, 15-19 and 22-23 stand rejected under 35 USC 102(b) for anticipation by Streckfus et al, US 6,294,349, issued September 25, 2001 as evidenced by Urban, "Use of Novel Technologies to Identify and investigate Molecular Markers for Ovarian Caner Screening and Prevention," http://cdmrp.army.mil/scripts/get_item.asp?item=abstract&log_no=OC970002&type=technical, publication date not established.

This rejection is traversed.

The examiner is requested to provide evidence of the publication date of Urban.

Claim 1 directed toward a cancer screening test employing a novel reagent containing antibodies made against a mixture of proteonic cancer markers. It is amended to require

that the markers are from different cell lines. The method enables one to nonspecifically determine the presence of any one of several proteonic cancer markers in saliva. Neither Streckfus et al nor Urban, nor their combination, even hints at employing a reagent made against a plurality of markers. Claim 1 patentably distinguishes the references by the recitation of "reagent containing antibodies made against a mixture of proteonic cancer markers from different cell lines". Claims 2-3 and 11-12 and 15 distinguish on this basis as well. Reconsideration and withdrawal of the 35 USC 102(b) rejection of these claims is requested.

Claim 2 further distinguishes the references by reciting, "in the ELISA test, the human saliva sample is coated on a plate prior to being brought together with the reagent." In Streckfus et al, antibodies are first coated on the plate. Urban does not disclose saliva assays.

Claim 15 further distinguishes the references by reciting "a plurality of antibodies".

Claims 16-19 are directed toward a cancer screening test employing a novel reagent "containing antibodies made against a plurality of proteonic cancer markers from different types of cancer cells". The method enables one to nonspecifically determine the presence of any one of several proteonic cancer markers in saliva. Neither Streckfus et al nor Urban, nor their combination, even hints at employing a reagent containing antibodies made against a plurality of proteonic cancer markers from different types of cancer cells. made against a plurality of markers. Claim 16 patentably distinguishes by the recitation of "containing antibodies made against a plurality of proteonic cancer markers from different types of cancer cells".

Claims 17-19 further distinguish by the recitation of "simple ELISA test", and by

requiring that the saliva sample be coated on the plate prior to being brought together with the reagent. Neither of the applied references disclose or suggest utilization of a simple ELISA test on saliva samples for the detection of positive test results. Reconsideration and withdrawal of the 35 USC 102(b) rejection of these claims is requested.

Claims 18-19 further distinguish by requiring that the markers employed be made from at least two cell lines selected from the recited group. The cited references fail to employ more than one. Reconsideration and withdrawal of the rejection of these claims is requested.

Claims 22-23 are directed toward evaluating the effectiveness of cancer treatment. Claims 22-23 distinguish the cited items by the recitation of "simple ELISA test". The meaning of "simple ELISA test" has furthermore been defined to distinguish over double antibody sandwich protocol. Reconsideration and withdrawal of the anticipation rejection of these claims is requested.

Rejections under 35 USC 103

Over Streckfus in view of Urban

Claims 1-3, 11-12, 15-19 and 22-23 stand rejected under 35 USC 103(a) for obviousness over Streckfus et al in view of Urban. This rejection is traversed.

The rejected claims distinguish the combined disclosures as pointed out above.

Both Streckfus et al and Urban are directed toward detecting specific biomarkers. For this purpose, separate assays are conducted with separate antibodies specific for the

biomarker being sought. In the invention(s) of claims 1-3, 11-12 and 15 "a reagent containing antibodies made against a mixture of proteonic cancer markers from different cell lines (is brought together with) with a human saliva sample to form an assay sample" (emphasis added). In claims 16-19, a "saliva sample (is brought together with) a reagent containing antibodies **made against a plurality of proteonic cancer markers** from different types of cancer cells to form an assay sample". (emphasis added). Both sets of claims enable a single assay to be conducted with more than one antibody, for the purpose of screening for the presence of any of a number of PCMs from a range of cancers. The identity of a specific PCM cannot be determined from the tests. The references would not lead one of ordinary skill in the art to conduct tests which failed to identify a particular PCM. The references therefore would not lead one of ordinary skill to employ a reagent "reagent containing antibodies made against a mixture of proteonic cancer markers from different cell lines" as required by claims 1-3, 11-12 and 15, or "a reagent containing antibodies made against a plurality of proteonic cancer markers from different types of cancer cells" as recited in claims 16-19, Reconsideration and withdrawal of the 35 USC 103 rejection made against these claims is therefore requested.

Claims 22-23 patentably distinguish the combined references by the employment of a "simple ELISA test". Claim 22 has furthermore been amended to recite "wherein, in the first and second simple ELISA tests, the saliva samples are coated on a plate prior to being brought together with the reagent". In Streckfus et al., a double antibody sandwich protocol is used, and antibody being positioned on the plate prior to the sample. In Urban, the proposed projects are to look, in serum rather than saliva, for differently expressed genes and for antibodies. A reagent "containing antibodies made against at least one proteonic cancer marker" would react with neither genes nor antibodies. The combination of references fails to makes out the elements of the claim, nor to render them obvious. Reconsideration and withdrawal of the 35 USC 103 rejection made against these claims is therefore requested

Claims 16-19 patentably distinguish the combined references by employing a novel reagent "containing antibodies made against a plurality of proteonic cancer markers from different types of cancer cells". In double antibody sandwich protocol as employed by Streckfus, the first antibody reacts with a first portion of the antigen, and the second antibody reacts with a second portion of the antigen not interfered with by binding between the antigen and first antibody. The purpose of the test is to identify specific markers. Utilizing a reagent containing antibodies made a plurality of markers would not be effective to do this. What is claimed is therefore submitted not be obvious from the combined references. Reconsideration and withdrawal of the rejection is therefore requested.

Over Streckfus in view of Urban further in view of Harlow et al and Cruse et al

Claims 4-10 and 13-14 stand rejected under 35 USC 103(a) as obvious over Streckfus in view of Urban further in view of Harlow et al (Antibodies, a Laboratory Manual, 1988, p. 142) and Cruse et al (Illustrated Dictionary of Immunology, 1995, page 241).

The disclosures of Harlow et al and Cruse et al fail to remedy the disclosures of the primary references. Claims 4-10 and 13-14 distinguish the combined disclosures of the four references on the same basis as previously pointed out concerning Streckfus and Urban.

Specifically, Harlow and Cruse fail to make obvious using mixtures of antibodies formed as set forth in claim 4 to conduct an assay.

Reconsideration and withdrawal of the 35 USC 103 rejection of these claims is therefore requested.

Rejections under 35 USC 112

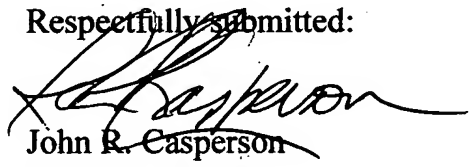
Claims 20-21 stand rejected under 35 USC 112, second paragraph, for indefiniteness based on the recitation "identifying a most highly positive result".

The rejection is traversed, but has been obviated by amending claim 20 to recite "identifying a test result outside of a predetermined range". Reconsideration is requested.

Conclusion

In view of the foregoing, reconsideration and withdrawal of all grounds of rejection and early notice of allowance is respectfully solicited.

Respectfully submitted:



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